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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/464,426	12/16/1999	CARLOS O. STALGIS	IN0964Q	7516

24265 7590 04/21/2003

SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER
FOLEY, SHANON A

ART UNIT	PAPER NUMBER
1648	17

DATE MAILED: 04/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/464,426	STALGIS ET AL.	
	Examin r	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *16* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

In paper no. 15, applicant cancelled claims 1-9 and added new claims 38-52.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 38-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albrecht (US 6,172,046 B1) or Albrecht (US 6,472,373), in the alternative. The previous rejection of the instant invention rendering the invention prima facie obvious in view of Albrecht (US 6,172,046) is maintained for reasons of record. New grounds of rejection, also rendering the invention prima facie obvious in view of Albrecht (US 6,472,373), is precipitated by applicant's submission of the reference in the IDS submitted 2/6/3.

The claims are drawn to a method of treating chronic HCV to eradicate detectable HCV-RNA measured by quantitative PCR (qPCR). The method comprises two treatment regiment periods. The first treatment regiment comprises administering 400-1600 mg per day of ribavirin and about 1.5 mg/kg of pegylated interferon-alfa-2b twice a week for at least about 4 weeks and up to about 12 weeks. The second treatment regiment comprises administering 800-1200 mg per day of ribavirin and about 0.5 to about 1.5 mg/kg of pegylated interferon-alfa-2b once a week for 36 to about 44 weeks. The claimed method eradicates detectable HCV-RNA for at least 24 weeks after the end of the second treatment period.

See the teachings of Albrecht (US 6,172,046 B1) discussed in the previous Office action.

Albrecht (US 6,472,373) teaches a method of treating HCV infection by administering 800-1200 mg per day of ribavirin and 0.5-2.0 mg/kg of interferon-alfa-2b per week, three times a week, five times a week or on a daily basis for a time period of about 40 to 50 weeks, wherein there is no detectable HCV-RNA for at least 24 weeks after the end of the treatment regiment. See column 2, line 45 to column 4, line 4, column 6, line 63 to column 7, line 2, the working examples drawn to administering the treatment combination for at least 48 weeks, claims 1-3, 7, 9, 13, 17 and 19.

Applicant argues that neither Albrecht patent anticipate or render obvious the treatment periods of the specified duration using the specific amounts of ribavirin or pegylated interferon alfa-2b recited in the claims.

Applicant's arguments have been carefully considered, but are found unpersuasive. It is conceded that neither Albrecht patent explicitly teach the dosing regiments recited in the claims, which is why the patents are not applicable under 35 USC 102. However, the treatment regiments taught by Albrecht (in either patent) encompass administering the amounts of ribavirin and pegylated interferon alfa-2b within the recited ranges for a time period equivalent to the combined duration of the treatment periods recited. Therefore, although neither patent explicitly teach the instant dosage regiment, one of ordinary skill in the art at the time the invention was made would have been motivated to choose specific dosage amounts throughout the treatment period lasting about 48 weeks (taught in each patent), depending on the type of hepatitis to be treated or to enhance the response of a patient to the therapy. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation for producing the claimed invention because it is routine in the medical arts to optimize dosage amounts and

duration of a substance for each individual patient and/or severity of disease. Each Albrecht patent disclose a range of effective amounts and time periods of administering ribavirin and pegylated interferon alfa-2b to eradicate detectable levels of HCV-RNA for at least 24 weeks after the last administration. Therefore, either Albrecht patent, in the alternative, renders the invention prima facie obvious, absent unexpected results to the contrary.

Conclusion

Applicant's amendment to the claims and applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 2/6/3 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § § 706.07(a) and 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley
April 15, 2003

JAMES HOUSEL 4/21/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600